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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,465	01/05/2006	Giuseppe Giannini	4865-80	1374
23117 7590 08/28/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER HAYLIN, ROBERT H				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
08/28/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/563,465

**Applicant(s)**

GIANNINI ET AL.

**Examiner**

ROBERT HAVLIN

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2 and 5-17 is/are pending in the application.  
4a) Of the above claim(s) 5-10 and 12-17 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1 and 11 is/are rejected.  
7) ☒ Claim(s) 2 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 05 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

**Status of the claims:** Claims 1, 2, and 5-17 are currently pending.

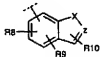
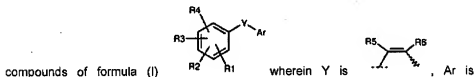
**Priority:** This application is a 371 of PCT/IT04/00373 (7/6/2004).

**RCE:** A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/28/08 has been entered.

### Election/Restrictions

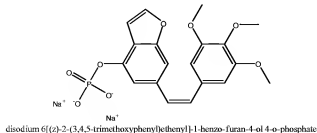
The election is as recited in the previous office action:

Applicants' election of Group (III), claims 1, 2 and 11, with traverse directed to



X is O, Z is CH, and the rest of the variables are as defined in a paper filed 06/25/2007 is acknowledged.

Applicant also elected the following species:



Because the generic claim encompassing the elected species was not found patentable (as detailed below), the claims are restricted to the elected species ONLY and the remaining subject matter held withdrawn.

***Response to Applicant's Arguments***

**112 Rejection**

1. Claims 1 and 11 were rejected under 35 USC 112, 2<sup>nd</sup> paragraph for being indefinite. Based on applicant's amendment to the claims clarifying the point of attachment of the R1-4 groups, this rejection is withdrawn.

**103 Rejection**

2. Claims 1 and 11 were rejected under 35 103(a) as being unpatentable over US 5,858,995 ("Kawai"). This rejection is maintained.

3. Applicant argues on page 16 of the response that the "present invention gives an additional feature which was not derivable from the prior art." This alleged feature appears to be the reduced toxicity and having no effect on blood pressure when compared to combretastatin A4 OR "the presence of a phosphate ester."

Considering both of these features, they are not actually part of the limitations recited in the claims and thus are not features relevant to the prior 35 USC 103 rejection. If applicant is arguing an unexpected result, the relevant comparison would be between the compounds of Kawai and not combretastatin. Applicant appears to assert that the disclosure of Kawai is not enabled because of a lack of working examples, however, unless there is evidence to the contrary there is a presumption of enablement for issued patents.

Therefore, applicant's arguments are not found persuasive and the rejection is maintained.

## **NEW CLAIM REJECTIONS**

### ***Claim Rejections - 35 USC § 102***

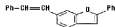
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3697513.

The prior art teaches the following compound



Which anticipates the claims when R1-6, R8-9 are H, and R10 is C6H5.

### **Claim Objections**

6. Claims 1, 2, and 11 continue to be objected to for reading on non-elected subject matter.

### ***Conclusion***

The claims are not in condition for allowance.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is

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(571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Robert Havlin, Ph.D.  
Examiner  
Art Unit 1626

/Kamal A Saeed, Ph.D./  
Primary Examiner, Art Unit 1626